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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,546	04/23/2001	William M. Hammesfahr	003BUS	6691

26830 7590 01/29/2003

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EXAMINER

JAWORSKI, FRANCIS J

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/841,546	HAMMESFAHR
	Examiner	Art Unit
	Jaworski Francis J.	3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 July 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- 4) Claim(s) 32-38 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 32-38 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

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The Substitute Specification filed 07-02-01 has been entered to the record

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 32 - 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 32, the language expressing a range of per cents of 'conventional dosage' is vague and indefinite insofar as individual patients vary widely in weight and sensitivity and side effects to such vasodilatory drugs that a 'conventional dosage' is not a definite term unless referenced to some standard.

With respect to claim 35, it is unclear what constitute 'Nitroglycerin equivalents', moreover parenthesized terms within claims are understood to be non-limiting. Returning to the former point, specification page 5 lines 4 - 7 defines certain such equivalents. Thereafter a broad variety of drugs are recited up to page 7 line 15 which references an additional appendix. Yet it is unclear if these are 'Nitroglycerin equivalents' in applicant's art-defined sense or if applicant is proferring that all of these listed medications are patent language equivalents for purposes of claims construal.

With respect to claims 36 and 37 the claims scope is wholly unclear. This case originally contained only claims 1 - 20, all cancelled per instructions in the Preliminary Amendment filed

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The Substitute Specification filed 07-02-01 has been entered to the record April 23, 2001 to cancel all prior claims. Therefore there is no claim 21 and no claim construable as being the parent claim to these claims for purposes of understanding their method scope.

With respect to claim 38, the preamble pertains to a 'titration system' whereas the body of the claim recites only method steps non-limiting on the titration system hence the scope is wholly unclear.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 32 - 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Panoz (US4592753) in view of Stanley et al (US4885173). The former teaches the use of a patch (col. 1 lines 33 - 68) of 2% nitroglycerin or clonidine ytransdermal delivery system for administration of these vasodilatory agents (col. 4 lines 7-13) including treatment of systemic diseases such as hypertension. It would have been obvious to provide usage/dosage instructions with a potent prescription drug, and for example user instructions are provided, see col. 2 lines 22 - 24 and 5 lines 14 - 16 .It would have been obvious in view of Stanley et al cols.5 - 6 and col. 8 lines 29 - 37 to titrate a vasodilator dosage in view of the patent's statements and side-effects stated.

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The Substitute Specification filed 07-02-01 has been entered to the record.

Renumbering of claims in consecutive order per Rule 126 has been held in abeyance pending understanding of status of claims 21-31 and antecedent reference made to claim 21 in the current claims.

1. Any inquiry concerning this communication should be directed to Examiner francis J. Jaworski at telephone number 703-308-3061..



Primary Examiner

FJJ:fjj

1-23-03